



Device Classification and Reclassification

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Preamendment vs. Postamendment Devices

The Act divided the arena of medical devices into either:

- Preamendment Devices or
- Postamendment Devices

Depending on when the devices were introduced into interstate commerce for commercial distribution

Classification of Preamendment Devices

Preamendment Devices are classified after FDA has:

- Received a recommendation from a device Classification Panel
- Published the Panel's recommendation for comment, along with a PR classifying the device; and
- Published a FR classifying the device

Reclassification of Preamendment Devices

FDA may reclassify a preamendment device:

- in a proceeding that parallels the initial classification proceeding
- based upon new information respecting a device either on FDA's own initiative or upon the petition of an interested person

Classification of Postamendment Devices

- Postamendment devices are automatically classified into Class III
- Those devices remain in Class III and require premarket approval, unless and until
 - the device is reclassified into Class I or II
 - FDA issues a SE determination
 - the device is classified into Class I or II via the Evaluation of Automatic Class III Designation (de novo review)

Reclassification of Postamendment Devices

- May be initiated by either FDA or Industry
- FDA may, for good cause shown, refer the petition to a device classification panel
- the Panel shall make a recommendation to FDA respecting approval or denial of the petition

Device Classes

A device should be placed in the lowest class whose level of control will provide reasonable assurance of safety and effectiveness

Class I - General Controls

Class II – General and Special Controls

Class III - Premarket Approval

Description of Classes

Class I – Mainly includes devices for which any combination of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of devices

General controls include, for example:

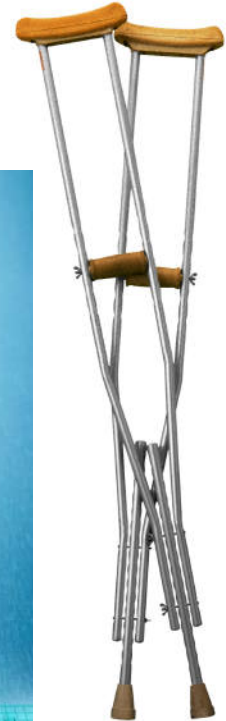
- prohibition against adulterated or misbranded devices

Description of Classes (continued)

- GMPs
- registration of manufacturing facilities
- listing of device types
- record keeping
- repair, replacement, refund
- banned devices

What are Some Examples of Class I Devices?

- Adhesive Bandages
- Manual Stethoscope
- Patient Scale
- Exam Light
- Crutches



Description of Classes (continued)

Class II

1. Devices which cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such device, and
2. For which there is sufficient information to establish special controls to provide such assurance

Description of Classes (continued)

Special Controls include, for example:

- Performance Standards
- Postmarket Surveillance
- patient registries
- development and dissemination of guidelines
- tracking requirements
- recommendations and other appropriate actions

What are Some Examples of Class II Devices?

- Ventilator
- Echocardiograph (ECG)
- Endoscope
- Hemodialysis System
- Surgical Sutures
- Syringes
- Powered Wheelchairs
- Computed Tomography (CT) Machines



How are Special Controls Used?

- As an example, for surgical sutures, FDA has issued a special controls guidance to mitigate risks to health:
 - Biocompatibility testing
 - Sterility testing
 - Conformance to the USP monograph
 - Resorption profile testing (for absorbable sutures)
 - Labeling (warnings, precautions, adverse reactions, etc.)
- These special controls, in combination with the general controls, provide reasonable assurance of safety and effectiveness
- Companies must provide evidence in their 510(k) submissions of how the special controls were addressed

Description of Classes (continued)

Class III

1. Devices for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the S&E of such device, and

Description of Classes (continued)

2. Such devices are
 - life sustaining and/or life supporting
 - substantial importance in preventing impairment of human health; or
 - present potential or unreasonable risk of illness or injury

What are Some Examples of Class III Devices?

- Implantable Pacemakers
- Implantable Spinal Cord Stimulators
- Contraceptive Intrauterine Devices (IUDs)
- Extended Wear Soft Contact Lenses

What are “Class III 510(k)” Devices?

- Preamendments devices where FDA issued a proposed rule classifying them as Class III; however:
 - No final rule was issued, or,
 - A final rule was issued for Class III, but the rule did not contain a date by which companies were required to submit a PMA
- Therefore, these Class III devices are allowed to proceed to market via the 510(k) process until such time as either a call for PMAs or a reclassification is finalized.

Restricted Devices

- Under the provision of Section 520(e) of FD&C Act, the FDA is authorized, by regulation, to restrict the sale, distribution, or use of a device if, because of its potentiality for harmful effect or the collateral measures necessary to its use, FDA determines there cannot otherwise be reasonable assurance of its safety and effectiveness.

Restricted Devices

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- A restricted device can only be sold, distributed, or used either
 - Upon the oral or written authorization by a licensed practitioner or
 - Under such other conditions specified by regulation.
- If the device is restricted to use by persons with specific training or experience in its use or by persons for use in certain facilities, FDA must determine that such a restriction is required for the safe and effective use of the device.

Restricted Devices

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- Devices such as cardiac pacemakers and heart valves, for example, require a practitioner's authorization.
- Hearing aids are restricted by a regulation which limits their sale to persons who have obtained a medical evaluation of their hearing loss by a physician within six months prior to the sale of the hearing aid. The labeling of hearing aids must provide information on their use and maintenance.